AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method of continuously analyzing trial data of an ongoing clinical trial, the method comprising the steps of:

accessing a trial database ~~containing~~ comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;

accessing a blinding database comprising subject identifiers and associated study group identifiers, wherein a subject's study group being identifiable by a study group identifier;

generating a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data of the subjects based on their study group;

performing a statistical analysis on the accessed trial database without suspending the ongoing blinded clinical trial;

determining whether the result of the statistical analysis exceeds a predetermined threshold value; and

if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating the steps of accessing a trial database, performing and determining while the blinded clinical trial is ongoing.

2. (Currently amended) The method according to claim 1, prior to the step of performing a statistical analysis, further comprising the steps of:

reading a user defined criteria that defines the level of cleanliness of the trial data for statistical analysis; and

retrieving only those trial data that meet the user defined criteria from the trial database.

3. (Currently amended) The method according to claim 1, further comprising the step of waiting for a predetermined time period prior to the repeating step ~~wherein~~ if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, ~~then waiting for a predetermined time period prior to the repeating step~~.

4. (Canceled)

5. (Currently amended) The method according to claim 1 [[4]], further comprising the step of storing ~~wherein~~ the grouped database ~~is stored~~ in a memory device that is inaccessible by any user.

6. (Original) The method according to claim 1, wherein the step of performing a statistical analysis is executed without locking the trial database.

7. (Currently amended) The method according to claim 1, ~~wherein the clinical trial is a blinded clinical trial~~, further comprising the steps of:

reading a predefined criteria that defines the level of cleanliness of trial data required for analysis; and

retrieving only those trial data that meet the predefined criteria from the trial database~~:~~

~~accessing a blinding database containing subject identifiers and an associated study group identifier for each subject, each study group identifier identifying to which study group each subject belongs; and~~

~~producing a grouped database from the retrieved trial data and the blinding database for statistical analysis, the grouped database grouping the trial data according to the study group~~.

8. (Currently amended) The method according to claim 7, further comprising the step of storing wherein the grouped database ~~is stored~~ in a memory device that is inaccessible by any user to preserve the blindness of the ongoing blinded clinical trial.

9. (Currently amended) The method according to claim 1, further comprising the step of alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.

10. (Original) The method according to claim 9, wherein the predetermined threshold value includes a predetermined statistical significance value.

11. (Currently amended) The method according to claim 10, wherein the step of performing a statistical analysis comprises the step of:

retrieving a user defined statistical model; and

running the retrieved user defined statistical model on the trial database.

12. (Currently amended) A method of continuously analyzing trial data of an ongoing blinded clinical trial, the method comprising the steps of:

accessing a trial database ~~containing~~ comprising blinded trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;

accessing a blinding database containing subject identifiers and associated study group identifiers, each study group identifier identifying to which study group an associated subject belongs;

producing a grouped database from the trial database and the blinding database, the grouped database grouping the trial data according to the study group;

performing a statistical analysis on the produced grouped database without suspending the ongoing blinded clinical trial;

determining whether the result of the statistical analysis exceeds a predetermined threshold value; and

if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value, then repeating the above steps of: accessing a trial database, producing a grouped database, performing a statistical analysis, and determining while the blinded clinical trial is ongoing.

13. (Currently amended) The method according to claim 12, prior to the step of performing a statistical analysis, further comprising the steps of:

reading a user defined criteria that defines the level of cleanliness of trial data for statistical analysis; and

retrieving only those trial data that meet the user defined criteria from the trial database for statistical analysis.

14. (Currently amended) The method according to claim 12, further comprising the step of ~~wherein~~ the produced grouped database is stored in a memory device that is inaccessible by any user.

15. (Original) The method according to claim 12, wherein the step of performing a statistical analysis is executed without locking the trial database.

16. (Currently amended) The method according to claim 12, further comprising the step of alerting a user if it is determined that the result of the statistical analysis exceeds the predetermined threshold value.

17. (Original) The method according to claim 16, wherein the predetermined threshold value includes a predetermined statistical significance value.

18. (Currently amended) A system for continuously analyzing an ongoing clinical trial comprising:

a storage device operable to store a trial database ~~containing~~ comprising trial data of subjects in an ongoing blinded clinical trial comprising a multi-arm study;

a processor coupled to the storage device; and

an analysis program executable by the processor and operable to:

access the trail database to retrieve the trial data;

access a blinding database comprising subject identifiers and associated study group identifiers, wherein a subject's study group being identifiable by a study group identifier;

generate a grouped database from the trial database and the blinding database for statistical analysis, the grouped database grouping the trial data of the subjects based on their study group;

perform a statistical analysis on the trial database without suspending the ongoing blinded clinical trial;

determine whether the output result of the statistical analysis exceeds a predetermined threshold value; and

repeat the statistical analysis while the blinded clinical trial is ongoing if it is determined that the result of the statistical analysis does not exceed the predetermined threshold value.

19. (Original) The system according to claim 18, wherein the analysis program is further operable to:

read a user defined criteria that defines the level of cleanliness of trial data for statistical analysis; and

retrieve only those trial data that meet the user defined criteria from the trial database.

20. (Original) The system according to claim 18, wherein if the analysis program determines that the result of the statistical analysis does not exceed the predetermined threshold value, then the analysis program waits for a predetermined time period prior to repeating the statistical analysis.

21. (Canceled)

22. (Currently amended) The system according to claim 18 [[21]], further comprising a memory device coupled to the processor and being inaccessible to any user, wherein the grouped database is stored only in the memory device.

23. (Original) The system according to claim 18, wherein the analysis program performs the statistical analysis without locking the trial database.

24. (Original) The system according to claim 18, wherein the analysis program is further operable to alert a user if it determines that the result of the statistical analysis exceeds the predetermined threshold value.